

**REMARKS**

Reconsideration and allowance are respectfully requested.

Applicants note for the record that no rejections of elected claims 1 to 61 and 65 have been made under 35 U.S.C. § 102, § 103, or § 112 in the Office Action mailed March 2, 2006. Accordingly, it is applicants' understanding that claims 1 to 61 and 65 are allowable, but for the Examiner's improper intra-claim restriction requirement discussed below.

Applicants also note for the record that the Examiner has given no indication that the restriction requirement between claim groups I, II, III, and IV, as defined by the Examiner in the Office Action mailed December 28, 2005, has been made final.

The Examiner has rejected claims 1 to 61 and 65 under 35 U.S.C. § 121 by improperly attempting to impose a restriction requirement under 37 CFR § 1.142(b) on elected claims 1 to 61 and 65 (claim group I):

Claims 1-61 and 65 (in part) are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR § 1.142(b).  
(Office Action, page 4, first paragraph)

However, there is no part of claims 1 to 61 and 65 that applicants have not elected (i.e., there is no non-elected subject matter in claims 1 to 61 and 65). Applicants further note for the record that the Examiner has given no indication that this improper intra-claim restriction requirement (in fact, a rejection of claims 1 to 61 and 65) has been made final.

While 37 CFR § 1.146 permits an Examiner to require an applicant to elect a single species within a generic Markush claim, as applicants have done in the paper filed on January 24, 2006, no authority exists for imposing a restriction requirement on the claims, effectively carving them up into various subparts. Pursuant to a proper restriction requirement, the Examiner has authority withdraw claims from consideration; the Examiner **cannot** withdraw **parts** of claims from consideration. The Examiner is acting contrary to the patent statutes, the caselaw, and the United States Patent and

Trademark Office prescribed procedures.

The Court of Customs and Patent Appeals ("CCPA") held in *In re Weber*, 580 F.2d 455, 458-49, 198 U.S.P.Q. 328, 331-32 (C.C.P.A. 1978), that the PTO cannot require an applicant, under the guise of 35 U.S.C. § 121, to divide up the embodiments of a single Markush claim. The invention in *Weber* related to cyclic diamine derivatives possessing a common psychotherapeutic property and identified by a single generic formula expressed in Markush format. The Examiner in that case found that the main claim embraced 24 enumerated independent and distinct inventions. He sought, as does the Examiner in the present application, to divide up the claim by rejecting it as an improper Markush claim and under 35 U.S.C. § 121 for misjoinder.

The court viewed the rejection as equivalent to a refusal to examine. 35 U.S.C. § 121 gives the PTO authority to restrict between claims of an application reciting one or more independent and distinct inventions. *In re Weber*, 580 F.2d at 458, 198 U.S.P.Q. at 331-32. It does not, however, provide authority to reject a generic claim on that basis, with the idea of requiring an applicant to break up the claim and present it in several applications. *Id.*, 198 U.S.P.Q. at 332. An applicant has a statutory right to claim an invention as he sees fit. *Id.* Accordingly, the court held that the PTO's rejection under 35 U.S.C. § 121 violated this statutory right. *In re Weber*, 580 F.2d at 458-59, 198 U.S.P.Q. at 332. See also *In re Watkinson*, 900 F.2d 230, 14 U.S.P.Q.2d 1407 (Fed. Cir. 1990), where the Federal Circuit confirmed the principle that the PTO cannot properly reject a single Markush claim under 35 U.S.C. § 121.

It is thus respectfully submitted that the Examiner's imposition of a restriction requirement within the presently elected claims (i.e., claims 1 to 61 and 65) is contrary to the law, as it is applicants' right to claim their invention as they see fit. The Examiner is attempting, in this application, to do exactly what the CCPA held to be improper in *In re Weber*.

The Examiner's imposition of a restriction requirement within the presently elected claims (i.e., claims 1 to 61 and 65) is also contrary to United States Patent and Trademark Office Procedures, as set out in the Manual of Patent Examining Procedure (MPEP). For the Examiner's convenience, applicants provide the entire text of MPEP §

803.02 in full below, with the most relevant passages in bold 14 point type:

**803.02 \* Markush Claims [R-3]**

**\*\*>**A Markush-type claim recites alternatives in a format such as “selected from the group consisting of A, B and C.” See *Ex parte Markush*, 1925 C.D. 126 (Comm’r Pat. 1925). The members of the Markush group (A, B, and C in the example above) ordinarily must belong to a recognized physical or chemical class or to an art-recognized class. However, when the Markush group occurs in a claim reciting a process or a combination (not a single compound), it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly responsible for their function in the claimed relationship, and it is clear from their very nature or from the prior art that all of them possess this property. Inventions in metallurgy, refractories, ceramics, pharmacy, pharmacology and biology are most frequently claimed under the Markush formula but purely mechanical features or process steps may also be claimed by using the Markush style of claiming. See MPEP § 2173.05(h).<

If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they **\*>**may be< directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require **\*>**provisional election of a single species<.

**Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re \*>Harnisch<*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature **\*\* essential to that utility.****

This subsection deals with Markush-type generic claims which **\*>**recite< a plurality of alternatively usable substances or members. In most cases, a recitation by enumeration is used because there is no appropriate or true generic language. A Markush-type claim **\*>**may< include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing **\*\*>**a Markush-type claim that encompasses at least two independent or distinct inventions<, the examiner may require a provisional election of a single species prior to examination on the merits. **\*\*>**An examiner should set forth a requirement for election of a single disclosed species in a Markush-type claim using form paragraph 8.01 when claims limited to species are present or using form paragraph 8.02 when no species claims are present. See MPEP § 808.01(a) and § 809.02(a).< Following election, the Markush-type claim

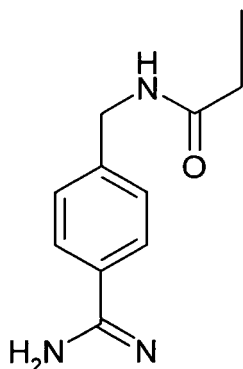
will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration. As an example, in the case of an application with a Markush-type claim drawn to the compound  $\text{X-R}$ , wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, XA, XB, XC, XD, or XE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration. A second action on the rejected claims can be made final unless the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97© with the fee set forth in 37 CFR 1.17(p). See MPEP § 706.07(a).

**On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended.** If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a *nonelected species*, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. **The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim.** In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action can be made final unless the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97© with the fee set forth in 37 CFR 1.17(p). See MPEP § 706.07(a). Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry if they do not comply with the requirements of 37 CFR 1.116. See MPEP § 714.13.

If a Markush claim depends from or otherwise requires all the limitations of another generic or linking claim, see MPEP § 809.

There is nothing in this section of the MPEP that authorizes the Examiner to create a subgenus to be examined, leaving the balance of the claimed compounds "withdrawn" from consideration. Indeed, as the discussion of Weber, Haas, Hozumi, and

Harnisch makes clear, it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. The compounds of the claimed invention possess unity of invention, in that they are all Factor VIIa inhibitors and share a substantial structural feature essential to the common function of the molecules, i.e.,



which can be further modified according to claim 1.

Thus, unity of invention has been established, and according to the MPEP the claims should be examined up to their full scope unless the Examiner determines that the claims are not patentable over the prior art. The Examiner has made no such determination in the present case.

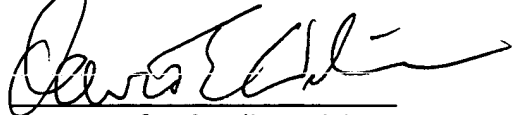
If it is the opinion of the Examiner that claims 1 to 61 and 65 represent improper Markush claims, then according to Hozumi and Harnisch, the Examiner can make an appealable REJECTION on this basis, but may not simply object to the claims and withdraw the purportedly nonelected portions of the claims from consideration.

Accordingly, the improper attempt to carve up claims 1 to 61 and 65 via a restriction requirement, which also serves as a rejection of claims 1 to 61 and 65, should be withdrawn. As no art rejections have yet been made in the present application, the Examiner should continue to search the full scope of elected claims 1 to 61 and 65, and issue a Notice of Allowance if he does not find any prior art that anticipates or renders obvious claims 1 to 61 and 65.

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Filed: November 21, 2003

No further fee is required in connection the filing of this Response. If any additional fees are deemed necessary, authorization is given to charge the amount of any such fee to Deposit Account No. 08-2525.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "David E. Wildman", written over a horizontal line.

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